UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/038,509	01/03/2002	Terry J. Smith	066742-0015	5468

41552 7590 10/04/2010

MCDERMOTT, WILL & EMERY LLP
600 13th Street, NW
Washington, DC 20005-3096

EXAMINER	
ROONEY, NORA MAUREEN	
ART UNIT	**PAPER NUMBER**
1644	

NOTIFICATION DATE	DELIVERY MODE
10/04/2010	ELECTRONIC

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

mweipdocket@mwe.com
SIP_Docket@mwe.com

Office Action Summary	Application No.	Applicant(s)	
	10/038,509	SMITH ET AL.	
	Examiner	Art Unit	
	NORA M. ROONEY	1644	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *29 July 2010*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1,3,6 and 7* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1, 3 and 6-7* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

1. Applicant's response filed on 07/29/2010 is acknowledged.

2. Claims 1, 3 and 6-7 are currently pending and under consideration as they read on a method of detecting Graves' disease in a patient comprising (a) obtaining an orbital or skin sample comprising fibroblasts from the patient, (b) contacting said fibroblasts with disease specific IgG from the same patient, and (c) detecting in said an orbital or skin sample binding of disease specific IgG to the IGF-1 receptor (IGF-1 R) relative to a control wherein said binding of disease specific IgG to the IGF-1 receptor (IGF-1 R) activates fibroblasts, wherein an increased presence of IgG-activated fibroblasts compared to the control indicates Graves' disease, and wherein fibroblast activation is determined by measuring the level of IL-16 expressed by said IgG-activated fibroblasts, RANTES expressed by said IgG-activated fibroblasts or by measuring T cell migration towards said fibroblasts in said orbital or skin sample.

3. In view of Applicant's amendment filed on 07/29/2010, only the following rejection is maintained.

Double Patenting

4. The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re*

Vogel, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent either is shown to be commonly owned with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement.

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

5. Claims 1, 3 and 6-7 stand rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1-4 of U.S. Patent No. 6,936,426 (PTO-892 mailed on 04/29/2010; Reference A) for the same reasons as set forth in the Office Action mailed on 04/29/2010.

Although the conflicting claims are not identical, they are not patentably distinct from each other.

Instant claims 1, 3 and 6-7 are drawn to : a method of detecting Graves' disease in a patient comprising (a) obtaining an orbital or skin sample comprising fibroblasts from the patient, (b) contacting said fibroblasts with disease specific IgG from the same patient, and (c) detecting in said an orbital or skin sample binding of disease specific IgG to the IGF-1 receptor

(IGF-1 R) relative to a control wherein said binding of disease specific IgG to the IGF-1 receptor (IGF-1 R) activates fibroblasts, wherein an increased presence of IgG-activated fibroblasts compared to the control indicates Graves' disease, and wherein fibroblast activation is determined by measuring the level of IL-16 expressed by said IgG-activated fibroblasts, RANTES expressed by said IgG-activated fibroblasts or by measuring T cell migration towards said fibroblasts in said orbital or skin sample of claim1; wherein an elevated level of the marker compared to the control indicates presence of said IgG-activated fibroblasts of claim 3; wherein the detecting is accomplished by exposing T-cells to said orbital or skin sample comprising said fibroblasts and measuring T-cell migration toward said fibroblasts, wherein an increase in the migration of said fibroblasts relative to the control indicates presence of said IgG-activated fibroblasts of claim 6; and wherein the patient is human of claim 7.

Claims 1-4 of U. S. Patent 6,936,426 are directed to: a method of detecting thyroid-associated ophthalmopathy in a patient comprising: obtaining a biological sample from the patient, isolating IgG from the patient sample, exposing the IgG to orbital fibroblasts from patients with thyroid-associated ophthalmopathy, measuring the level of IL-16 or RANTES produced by the orbital fibroblasts, wherein an elevated level of IL-16 or RANTES, as compared to normal control indicates the presence or severity of thyroid-associated ophthalmopathy in the patient of claim 1; wherein the level of IL-16 or RANTES is measured by an Enzyme-Linked Immunosorbent Assay (ELISA) of claim 2; wherein the patient is human of claim 3; and wherein the biological sample is selected from the group consisting of: blood, synovial fluid, ascites, and tissue of claim 4. It is noted that thyroid-associated ophthalmopathy is present in Graves Disease

patients. Therefore, the same method is being performed in the same patient population for the same result.

Applicant's argument filed on 07/29/2010 has been fully considered, but is not found persuasive.

Applicant argues:

> "Claim 1 has been amended to clarify that the claimed methods require detection of binding of the disease-specific antibodies to the IGF-1R autoantigen. Patent No. 6,936,426 neither teaches nor suggests even the identity of the autoantigen responsible for the autoimmune response in Graves Disease. Removal of the rejection of claims 1, 3, 6-7 and 9-11 on the ground of non-statutory obviousness-type double patenting over claims 1-4 of U.S. Patent No. 6,936,426 is respectfully requested."

It is the Examiner's position that the active steps of instant claims 1, 3 and 6-7 are the same as claims 1-4 of the 6,936,426 patent. In the method of claims 1-4 of 6,936,426, Graves Disease specific IgG has inherently bound the IGF-I receptor and activated the fibroblasts. There is no difference between the active method steps or the patient populations. Therefore, the results are inherent. Applicant is attempting to rely on a previously unappreciated property of the activation step of the method in order to make the method patentably distinct. IGF-1 receptor specificity of Graves Disease Specific IgG is an intrinsic property of the Graves Disease Specific IgG. See In re Cruciferous Sprout Litigation, 301 F.3d 1343, 64 USPQ2d 1202 (Fed. Cir. 2002). There are no active steps that make the instant method of claims 1, 3 and 6-7 any different than that of claims 1-4 of Patent 6,936,426. The method performed with or without the knowledge of IGF-1 receptor specificity of Graves Disease Specific IgG still results in the measurement of fibroblast activation by measuring IL-16, RANTES or T-cell migration and a detection of Graves Disease.

6. No claim is allowed.

7. **THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

8. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Nora M. Rooney whose telephone number is (571) 272-9937. The examiner can normally be reached Monday through Friday from 8:30 am to 5:00 pm. A message may be left on the examiner's voice mail service. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Ram Shukla can be reached on (571) 272-0735. The fax number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

September 29, 2010

Nora M. Rooney
Patent Examiner

Technology Center 1600

/Nora M Rooney/

Primary Examiner, Art Unit 1644